STATE OF WISCONSIN
SUPREME COURT

STATE OF WISCONSIN,

Plaintiff-Respondent-Cross-Appellant,

v.

ABBOTT LABORATORIES, ASTRAZENECA LP, ASTRAZENECA PHARMACEUTICALS LP, AVENTIS PHARMACEUTICALS, INC., BEN VENUE LABORATORIES, INC., BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., BOEHRINGER INGELHEIM ROXANE, INC., BRISTOL-MYERS SQUIBB CO., DEY, INC., IVAX CORPORATION, IVAX PHARMACEUTICALS, INC., JANSSEN LP f/k/a JANSSEN PHARMACEUTICAL PRODUCTS, LP, JOHNSON & JOHNSON, INC., MCNEIL-PPC, INC., MERCK & CO. f/k/a SCHERING-PLOUGH CORPORATION, MERCK SHARP & DOHME CORP. f/k/a MERCK & COMPANY, INC., MYLAN PHARMACEUTICALS, INC., MYLAN, INC. f/k/a MYLAN LABORATORIES, INC., NOVARTIS PHARMACEUTICALS CORP., ORTHO BIOTECH PRODUCTS, LP, ORTHO-MCNEIL PHARMACEUTICAL, INC., PFIZER INC., ROXANE LABORATORIES, INC., SANDOZ, INC. f/k/a GENEVA PHARMACEUTICALS, INC., SICOR, INC. f/k/a GENSIA SICOR PHARMACEUTICALS, INC.,

Appeal No.
2010AP232-AC

SMITHKLINE BEECHAM CORP. d/b/a GLAXOSMITHKLINE, INC., TAP PHARMACEUTICAL PRODUCTS, INC., TEVA PHARMACEUTICALS USA, INC., WARRICK PHARMACEUTICALS CORPORATION, WATSON PHARMA, INC. f/k/a SCHEIN PHARMACEUTICALS, INC. and WATSON PHARMACEUTICALS, INC.

Defendants,

PHARMACIA CORPORATION,

Defendant-Appellant-Cross-Respondent.

On Appeal from the Circuit Court for Dane County
Case No. 04-CV-1709
The Honorable Richard G. Niess Presiding

THE NON-PHARMACIA GENERIC DEFENDANTS' *AMICUS CURIAE* BRIEF

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INTRODUCTION

This Court has accepted review of three certified questions for this appeal. Because the Court's decision may impact the issues to be presented in later trials asserting similar claims against other pharmaceutical manufacturers, Generic Defendants[1] submit this brief to assist the Court in its determination of one of the certified questions – whether Wisconsin's damage theory required the jury to speculate.

Generic Defendants support the arguments set forth by Pharmacia on appeal. Generic Defendants submit this brief to provide the Court with relevant history of generic pharmaceutical reimbursement both generally under federal regulations governing state Medicaid programs and specifically under Wisconsin's Medicaid reimbursement system. Generic Defendants submit that this information is of vital importance when considering the damage question certified and the potential impact of a decision on Generic Defendants.

The State's central claim in this case is that published "Average Wholesale Prices" ("AWPs") should have been "actual" prices, and that had Wisconsin's Medicaid program received such "true" AWPs, it would have paid less money to pharmacies when reimbursing for pharmaceuticals

[1] Generic Defendants are Teva Pharmaceuticals USA, Inc., Ivax Corporation, Ivax Pharmaceuticals, Inc., Sicor Inc., Sandoz Inc., f/k/a Geneva Pharmaceuticals, Inc., Mylan Pharmaceuticals Inc., Mylan Inc., f/k/a Mylan Laboratories Inc., Watson Pharmaceuticals, Inc. and Watson Pharma, Inc., f/k/a Schein Pharmaceutical, Inc.

dispensed to Medicaid patients. For two reasons pertinent to Generic Defendants, the State's damage theory is wholly speculative. First, for the vast majority of generic drugs, Wisconsin established a Maximum Allowable Cost ("MAC"). Where a MAC existed, Wisconsin reimbursed for ingredient cost at the MAC, which was set by Wisconsin without regard to AWP. Because these generic drugs were not reimbursed based on AWP, inflated AWPs would not cause any damage. Wisconsin's argument to the contrary – that if AWPs had been accurate Wisconsin would have reimbursed at AWP rather than MAC and would not have made the conscious decision to reimburse at an amount greater than that paid for the drugs – requires the Court and the jury to engage in pure speculation regarding what reimbursement scheme Wisconsin would have adopted.

Second, the State's damages analysis assumes that for all drugs (whether or not they were subject to a MAC), Wisconsin was constrained by federal regulations to reimburse for ingredient cost at no more than the average price paid by pharmacies. It is only by assuming this constraint that the State could posit the price that it maintains Wisconsin would have paid but for defendants' alleged misconduct. During the years at issue in this case, however, the constraint did not exist. Since 1987, federal regulations have permitted a state to reimburse for ingredient cost at an amount greater than what pharmacies paid on average. In fact, federal regulations encouraged state Medicaid programs to use ingredient

reimbursement profits as an incentive for pharmacies to substitute less expensive generic drugs for costlier brand name counterparts and thereby save Medicaid money.

FACTUAL BACKGROUND

In order to promote the development, production and marketing of affordable generic medicines, Congress enacted the Hatch-Waxman Act in 1984. *See* 21 U.S.C. § 355(j). Hatch-Waxman, among other things, established an expedited review process by the Food and Drug Administration for generic drugs, which created significant incentives for generic manufacturers to enter the market. *See Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 879 (D.C. Cir. 2004).

Hatch-Waxman has had its intended effect in the marketplace. The availability of less expensive generic substitutes to brand-name pharmaceuticals has increased substantially in the last quarter century, bringing cost savings to government programs (including Medicaid), private insurance plans, and consumers. *See* R. 439, pp. 40:19-43:7.

Even before Hatch-Waxman was enacted, Wisconsin was using a MAC program to take advantage of cost savings from generics. Wisconsin has estimated that by "aggressively" establishing MACs for approximately 1,300 national drug codes (NDCs), *see* R.139, Ex. 22 at 29:5-30:1; R.139, Ex. 20 at 112:14-113:19, it has over the years saved "probably hundreds of

millions" of dollars for Wisconsin taxpayers, *see* R.139, Ex. 20 at 110:7-111:2.

Employees of Wisconsin Medicaid explained that to establish MACs for generic drugs, Wisconsin Medicaid does not rely on published prices of any sort, including AWPs. *See* R.139, Ex. 20 at 101:11-102:10, 128:11-16, 129:3-16, 131:7-132:5, 132:14-22; 160:16-161:15, 184:19-21. Instead, Wisconsin Medicaid researches the actual transaction prices at which generic drugs are being sold in the marketplace by obtaining pricing information directly from drug wholesalers, group purchasing organizations, state agencies and pharmacy invoices. R.139, Ex. 20 at 62:15-64:17, 203:19-204:9, 221:9-17, 242:7-11; R.139, Ex. 22 at 23:10-24:7. Armed with net prices for generic drugs, Wisconsin Medicaid then adds a 10-25% markup to the lowest net price to set that drug's MAC, which forms the basis for reimbursement for any drug that is subject to it. Adding this markup to a drug's net price ensures that pharmacists have an incentive to continue participation in the Wisconsin Medicaid program, which is significant because Wisconsin is required, under federal regulations, to balance the need to control costs with the obligation to ensure that Medicaid beneficiaries have the same access to services as those in the broader community. *See* 42 U.S.C. § 1396a(a)(30); R.139, Ex. 20 at 74:9-18 (markup guaranteed that MAC administrator would not receive "800 phone calls" from pharmacists complaining about the MAC price);

R.139, Ex. 22 at 27:3-9 (MAC administrator explained that the markup was established to "ensure access"). *See also* R.139, Ex. 11 at 1-2; R.139, Ex. 14 at 6-7. By so doing, Wisconsin Medicaid takes full advantage of lower prices from generic competition. *See* R.139, Ex. 11 at 1-2; R.139, Ex. 14 at 6-7. 9, Ex. 14 at 6-7.

DISCUSSION

I. Plaintiff's Damage Theory Required the Jury to Speculate Regarding an Alternative to Wisconsin's MAC Program

In its certification memorandum, the Court of Appeals characterized the issue for this Court as one involving the sufficiency of proof of damages. Cert. Memo. at 9. Under Wis. Stat. §100.18(1), to establish the fact of damages (causation), Wisconsin must show that, but for a defendant's false statement, it would not have been induced to do what it did, and would not have suffered a resultant injury. *Novell v. Migliaccio*, 2008 WI 44, ¶ 49, 309 Wis. 2d 132, 749 N.W.2d 544; Wisconsin JI-Civil § 2418. If the Court determines that Wis. Stat. § 49.49(6) is a damages claim, Wisconsin similarly must show damages by sufficient proof.

Wisconsin's theory is that it paid more to Medicaid providers for dispensing drugs than it otherwise would have had Pharmacia not caused "false" or "inflated" AWPs to be published. Resp. Br. at 19. Plaintiff contends that, "Wisconsin knew that published AWPs needed discounting, but lacked authoritative information on how big the discount needed to be."

Id. at 14. As a result, Wisconsin alleges that it was left to rely on AWP because "it was not practical for Wisconsin itself to gather the data," and that those "false AWPs" caused "excessive reimbursement to pharmacies." *Id*. at 2, 8.

This argument is inapplicable to generic pharmaceuticals reimbursed at MACs. Wisconsin Medicaid employees testified that AWPs have *nothing whatsoever* to do with Wisconsin Medicaid's MAC reimbursement. *See* R.139, Ex. 20 at 8:9-17, 23:14-21, 160:16-161:15, 245:21-246:16; R.139, Ex. 22 at 24:8-16. Rather than relying on published AWPs when setting MACs, Wisconsin Medicaid began by obtaining pricing information directly from various drug wholesalers, group purchasing organizations, other state agencies and pharmacist invoices to set MACs. *Supra* at 4. The administrator of the MAC program, Ted Collins, testified that after that pricing information was collected he personally searched for the lowest price for each generic drug that was readily available in the marketplace, and then set the MAC by adding a 10-25% markup to that price. *See* R.139, Ex. 20 at 16:3-17:14, 74:9-18, 95:20-96:3; R.139, Ex. 22 at 25:14-27:9. Thus, by Wisconsin's own admission, the AWPs that it now claims were "deceptive" played no role in reimbursing providers for dispensing the vast majority of generic drugs. Consequently, Wisconsin cannot demonstrate the requisite "causal connection between the [allegedly] untrue, deceptive, or misleading representation" purportedly "made to

induce action" with respect to the vast majority of generic drugs reimbursed by Wisconsin. *K&S Tool & Die Corp. v. Perfection Mach. Sales, Inc.*, 2007 WI 70, ¶35, 301 Wis. 2d 109, 732 N.W.2d 792 (citing Wis. Stat. § 100.18(1) and *Kailin v. Armstrong*, 2002 WI App. 790, 252 Wis. 2d 676, 643 N.W.2d 132).

Wisconsin contends that causation is not defeated because it "offered evidence that [Wisconsin] would have used accurate AWPs, had it received them, to set [MACs]." Resp. Br. at 16. That argument is inconsistent with Wisconsin's decision to reimburse providers for generic drugs at levels that reflected a 10-25% markup over actual market prices, plus a reasonable dispensing fee. Wisconsin set its MACs at a markup over market prices to ensure that every pharmacy could purchase the drug at or below the MAC rates. *See* R. 139, Ex. 11 at 1-2; R. 139 Ex. 20 at 74:9-18; R. 139, Ex. 22 at 27:3-9. A jury would be asked to speculate that Wisconsin would not have adopted the MAC program that it did, and that it would have reached a different decision regarding providing a mark-up to pharmacies if it had used AWPs as a reflection of market prices rather than the data-analysis results that it did use. In doing so, the jury would be forced to speculate that Wisconsin would have been willing to reimburse at an amount less than the price that would have been "uniformly available" to all providers (both large retail chains and independent pharmacies) in Wisconsin (Resp. Br. at 17), because by definition some pharmacies will pay more and some

will pay less than the average price. Such speculation would not only be contrary to what Wisconsin did in connection with the MAC program, it would be inconsistent with the federal mandate to ensure that Medicaid beneficiaries have the same access to services as those in the broader community.[2] *See* 42 U.S.C. § 1396a(a)(30); R.139, Ex. 20 at 74:9-18; R.139, Ex. 22 at 27:3-9.

II. The 1987 Revisions To The Federal Medicaid Regulations Permitted (And Encouraged) States to Reimburse Above Cost for Generic Drugs

As discussed above, the overwhelming majority of reimbursements paid by Wisconsin for generic drugs are based on Wisconsin's MAC rates. For generic drugs with no applicable MAC or FUL,[3] Wisconsin reimburses based on the lesser of the State's Estimated Acquisition Cost ("EAC") plus a reasonable dispensing fee, or the pharmacist's usual and customary charge to the general public. *See* 42 C.F.R. §§ 447.331 - 447.332.[4] Throughout the time period relevant to this lawsuit, the Wisconsin

[2] Any argument that Wisconsin would not have even had a MAC program and reimbursed all generic drugs using an AWP formula that employed "true" AWPs, or that an AWP formula using "true" AWPs would have produced lower amounts than the MACs and made them irrelevant, invites even greater speculation as to what Wisconsin would have done, as explained in Appellant's opening brief. See Appellant Br. at 28-36. That is, the jury would be forced to speculate that Wisconsin would have abandoned the explicit goal of the MAC program and instead have chosen to reimburse at a rate that would cause all pharmacies paying more than the average price to either withdraw from the program or lose money.

[3] The federal government sets specific upper limits on generic drugs called Federal Upper Limits ("FULS") pursuant to 42 C.F.R. §447.332. FULs are set by applying a 50% markup to published prices.

[4] The federal regulations were revised and renumbered in 2005. References herein are to the regulations prior to those changes.

legislature set its EAC at the published AWP minus a discount ranging from 10% to 13%.

Wisconsin maintains that the jury was not required to speculate about the amount at which it would have reimbursed for generic drug ingredient costs because it was constrained by federal regulation to reimburse at no more than EAC, which was defined as the State's best estimate of actual prices paid by pharmacies. In fact, federal regulations were not so limiting, and they encouraged states to provide a mark-up or profit margin when reimbursing for generic drugs to encourage the use of such drugs rather than their more expensive branded counterparts.

A. The Pre-1987 Reimbursement Regulations

Before 1987, federal regulations set a specific limit on the amount a state could pay for each reimbursement claim submitted by a pharmacist. The regulations restricted states from reimbursing more than the product's "ingredient cost" plus a dispensing fee: "The agency may not pay more for prescribed drugs than the lower of the ingredient cost plus a dispensing fee or the provider's usual and customary charge to the general public." 42 C.F.R. § 447.331(a) (1979); 43 Fed. Reg. 45253, 45261 (1978). Under this regulatory regime, "ingredient cost" refers to the cost of the drug and "cost" was defined in § 447.332 for multiple-source drugs and all other drugs. 42 C.F.R. §§ 447.332, 447.333 (1979); 43 Fed. Reg. at 45261. Regulations further required states to base dispensing fees on surveys of pharmacy

operation costs, and placed specific limitations on how dispensing fees could vary. *See* 42 C.F.R. § 447.333 (1979); 43 Fed. Reg. at 45261.

B. The 1987 Revisions To The Reimbursement Regulations Increased State Flexibility

In 1983, a Departmental Task Force was created to review HCFA's drug reimbursement regulations resulting in a thorough revision of the regulations in 1987. *See* 42 C.F.R. § 447.331 (1987); 52 Fed. Reg. at 28648-58. Notably, HCFA confirmed its understanding that published prices "often overstated" actual costs.[5] *Id.* at 28650. HCFA's revised regulations eliminated any requirement that each and every drug be reimbursed based on its cost. The Official Comments to the Regulations confirm this rule was eliminated to account for and take advantage of declining generic prices. *Id.* at 28648 ("This rule enables the Federal and State governments to take advantage of savings that are currently available in the marketplace for [generic] drugs."); *see also id*. at 28654.

In addition, sections 447.331 and 447.332 were re-written to eliminate the specific per-prescription payment limit. In their place, HCFA set separate, broad aggregate limits for (1) multiple-source drugs subject to an FUL; and (2) all other drugs. *Id.* Each state was required to certify that

[5] At least by 1984, HCFA knew that AWP was not an actual average of prices charged, because the Office of Inspector General (OIG) for the U.S. Department of Health & Human Services (HHS) then advised the agency that AWP was a list price that does not reflect discounts and price concessions. R. 304, DX 519.

its drug reimbursement payments did not exceed the aggregate limits. *Id.*; 52 Fed. Reg. at 28657-58.

The revised regulations also eliminated the provision governing how dispensing fees should be set and provided only that the states should take into account a "reasonable" dispensing fee when determining whether their payments were within the aggregate upper limits. 42 C.F.R. §§ 447.331(b), 447.332(b) (1987); 52 Fed. Reg. at 28658. As the HHS Departmental Appeals Board held, this provision permitted states to "offset a lower than reasonable dispensing fee with ingredient costs which were higher than HCFA's specific limits." Pennsylvania Dep't of Public Welfare, DAB No. 1315, at p. 8 and 9 n.9 (Mar. 18, 1992), available at http://www.hhs.gov/dab/decisions/ dab1315.html; *see also id*. at 12; *Pennsylvania Pharm. Assoc. v. Casey*, 800 F. Supp. 173, 176 (M.D. Pa. 1992) (concurring in HHS Departmental Appeals Board's conclusion).[6]

Moreover, while the regulations continued to use EAC, *that figure did not apply to drugs subject to an FUL*. 42 C.F.R. § 447.332. Even when the EAC did apply, it was applied in the aggregate with the dispensing fee, across all relevant drugs, and not as a per-prescription payment limitation. As HCFA stated in the comments to the new rule, "[u]nder this rule, the

[6] Wisconsin cannot distinguish the Pennsylvania decision (Resp. Br. at 28-29, n.3) by citing to a follow-up appeals board decision refusing to allow Pennsylvania to adjust its dispensing fee for a year that had already passed, as that later decision neither overturned nor addressed the relevant holding from the prior Pennsylvania decision: that a state may offset a low dispensing fee with higher ingredient cost reimbursement.

EAC criteria are applied as an upper limit on an aggregate basis rather than on a prescription by prescription basis." *See* 52 Fed. Reg. at 28652. The FUL limits for multiple source drugs likewise applied "in the aggregate." 42 C.F.R. § 447.332(b). The aggregate criteria in the 1987 regulations, therefore, eliminated any requirement that each individual drug be reimbursed at "cost" while attempting to provide states with greater flexibility in administering their reimbursement programs. 52 Fed. Reg. 28655.

The practical effect of the new regulations was that states could now pay whatever they wanted to reimburse for a particular drug, so long as their aggregated total reimbursement payments (including dispensing fees) for each of the two categories of the drugs did not exceed the prescribed upper limits.[7] HCFA's comments to the new rules confirmed this: "States will be free to make payments for individual drugs on any reasonable basis as long as … payments … do not exceed the aggregate." 52 Reg. at 28655.

Further, HCFA acknowledged the important role profits play in creating an incentive for pharmacies to substitute less expensive generic drugs for brand name products, thereby saving the Medicaid program money. In its comments, HCFA explained the importance of financial

[7] This point is not merely academic. As set forth in Pharmacia's appellant brief, Wisconsin's dispensing fees were well below dispensing costs and, viewed alone, they were inadequate to encourage providers to participate in Medicaid. *See* Appellant Br. at 8, n.3, 16-17, 19, 20, 32.

incentives in state MAC programs, which HCFA encouraged states to continue to use:

> We hope that the State agencies will be innovative in these programs and find ways to assure the availability at reasonable prices for multiple-source drugs. One way they could do this would be to encourage retail pharmacy participation in the Medicaid program by ***permitting them to retain profits*** from the sale of listed drugs to Medicaid recipients.

52 Fed. Reg. at 28653 (emphasis added).

Wisconsin argues that it could not have reimbursed for ingredient cost at more than the average price pharmacies paid for ingredients, had it known those prices. It bases this argument on the federal definition of EAC, which is defined as a state's best estimate of prices pharmacies generally and currently pay for a drug. *See* Resp. Br. at 14. As shown, this argument is incorrect with respect to generics because (1) EAC did not apply to generic drugs subject to an FUL, and (2) when it did apply, the EAC limit applied "in the aggregate," across all relevant drugs and payments, including dispensing fees, such that Wisconsin was not prohibited from including the necessary margins in the ingredient cost reimbursement.

Profit to pharmacy providers was therefore both an important part of, and sanctioned by, the federal government for the Medicaid prescription drug reimbursement program. Generic Defendants urge the Court to consider these policies when deciding the damages issue before it.

CONCLUSION

This Court should reverse the judgment of the circuit court and order that the jury verdict be vacated.

Dated this 6th day of October, 2011.

Attorneys for Defendant Sandoz Inc.

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Submitted on Behalf of all Non-Pharmacia Generic Defendants

CERTIFICATION OF FORM AND LENGTH

I hereby certify that this brief conforms to the rules contained in §809.19(8)(b) and (c) for a brief and appendix produced with a proportional serif font. The length of this brief is 2,819 words.

Dated this 6th day of October, 2011

_____

Shannon A. Allen (SBN: 1024558)

CERTIFICATE OF COMPLIANCE WITH RULE 809.19(12)

I hereby certify that I have submitted an electronic copy of this brief which complies with the requirements of s. 809.19(12). I further certify that the electronic brief is identical in content and format to the printed form of the brief filed as of this date.

Dated this 6th day of October, 2011

_____

Shannon A. Allen (SBN: 1024558)

CERTIFICATE OF SERVICE

I hereby certify that on the 6th day of October, 2011, pursuant to § 809.80(3)(b) and (4), Wis. Stats., the original and twenty-one (21) copies of the foregoing Non-Pharmacia Brand Defendants' *Amicus Curiae* Brief were delivered to the Clerk of the Wisconsin Supreme Court via messenger, correctly addressed. I further certify that three (3) copies of the same were served upon the persons listed below by depositing in the United States mail for delivery by first-class mail, correctly addressed and postage prepaid:

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I further certify that all other counsel of record have been served today electronically, via Lexis Nexis File and Serve®.

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